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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,540	08/09/2001	Swaminathan Jayaraman	10588-007	1989

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,540	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-19,26,31-35,37 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-19,26,31-35,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and remarks dated 8-19-04 is acknowledged.

Claims 3-19, 26, 31-35, 37 and 38 are pending in the instant application.

The following rejection of record has been maintained:

1. Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

2. Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a filter bag coated with aspirin or sildenafil citrate, does not reasonably provide enablement for a filter bag coated with any pharmaceutical, beneficial agent or a supplemental nutrient.

Response to Arguments

Applicant's arguments filed 8-19-04 have been fully considered but they are not persuasive.

Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicants argue that examiner has failed to meet the initial burden by failing to present evidence or reasons why a person in the art would not recognize the written description of the invention provides support for the claims. In support for their argument that instant claims meet the written description requirement, Applicants cite portions of

MPEP that states each claim should be evaluated to determine if sufficient structure, acts or "functions" are recited to make clear the scope and meaning of the claim; and that absence of definitions or details for well established procedures should not be the basis of a rejection for lack of adequate description. Applicants also argue that generic classification of various categories of agents listed are well know to persons of ordinary skill in the art, as supported by their GOOGLE search results. Applicants further argue that both claims and specification are equal in the breadth and teach that medicament used for coating the filter bag material is present in a therapeutically effective amount and may include any of the beneficial agents listed. Applicants' arguments are not found persuasive because while it is true that various categories of agents are known to one of an ordinary skill in the art, in order to meet written description requirement it is not sufficient to just to show that the agents claimed are known to one of an ordinary skill in the art but the specification should convey the information that an applicant has invented the subject matter and to put the public in possession of what applicants claimed as their invention by adequately describing their inventions in sufficient detail. In this respect, instant specification fails to describe the details of beneficial agents, as to how these various categories of beneficial, each of which is also know in the art to be different in their nature, function, property etc., are incorporated in the membrane of the filter bag. While it is true that applicants described a few compounds in the instant specification, instant claims also recite other beneficial agents such as an anti-oxidant, which is extremely broad because the term anti-oxidant includes a very wide range of chemical substances that do not necessarily have a common structure or chemical

property. Similarly the claimed agents include phytochemical, diagnostic agents, an enzyme etc., which are very different chemical substances and are very huge molecules with varying therapeutic dosages from very low to very high amounts. The very terms probiotics, diagnostic, enzyme etc., constitute a huge genus of compounds that are not necessarily related in structure or function or both. . Further, the instant specification does not provide as to amounts of medicinal agents incorporated in to the filter bag. Furthermore, a mere functional description of beneficial agents without any known or disclosed correlation between the function and the structure would not constitute a sufficient written description. While a number of beneficial or medicinal agents are known to one of an ordinary skill in the art (as shown in GOOGLE search), the question here is whether applicants are in possession of all these beneficial agents incorporated in the filter bags at the time of the instant invention. It is therefore, the position of the examiner that applicants have not met the burden of written description requirement and thus does not clearly allow persons of ordinary skill in the art to recognize that applicants are in possession of what is claimed at the time of the instant invention.

Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a filter bag coated with aspirin or sildenafil citrate, does not reasonably provide enablement for a filter bag coated with any pharmaceutical, beneficial agent or a supplemental nutrient.

Applicants' argument that instant application describes beneficial compounds listed on page 6, lines 14-24 is acknowledged. 24). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 1 12 is satisfied. Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid. Applicants submit that the method of making and using a filter bag coated with any of the above identified specific examples bears a reasonable correlation to the method of making and using a therapeutically effective amount of at least one medicinal agent on a filter bag. It is also argued that the medicinal agent of claim 37 is selected from the group consisting of a pharmaceutical (aspirin), supplemental nutrient (eucalyptus), a beneficial agent vitamin and a combination thereof and for each one of these groups, the specification sets forth at least one specific example (identified in the parenthetical). Accordingly, applicants argue that that claims 3-19, 26, 31-35 and 37 meet the enabling requirement.

Applicants' arguments have been considered but not found persuasive because instant specification provides no guidance as to how to prepare the medicament such that it is incorporated in the bag material i.e., as a powder or solubilized and applied a liquid coating etc. Instant claims recite various categories of compounds such as probiotics, therapeutics, diagnostic agents etc. Instant specification describes that a therapeutically effective amount of the medicinal or beneficial agent is incorporated in the membrane of the filter bag. However, a search of the therapeutic dosages of a few therapeutic compounds such as glucophage (a specific compound of anti-diabetic)

shows that certain drugs are given at a concentration as high as 850 mg in a single oral dose. Similarly, a single dose of antibiotic may contain upto 925 mg (augmentin) of the therapeutically active compound. Further, the instant claimed therapeutic or beneficial agents such as a diagnostic or phytochemical or anti-oxidant etc., include compounds of different structure and nature. In other words, the claimed therapeutic compounds may be highly hydrophilic or highly lipophilic or even heat sensitive etc. Applicants have not described if all of the materials claimed i.e., drugs or nutrients or other beneficial agents, are soluble upon contact with liquid, or any mechanism as to how the medicaments claimed are released. Applicants have also not described or provided any guidance to incorporate such high amounts of a huge genus compounds or therapeutic agents without loosing their activity upon preparing the beverage in the desired liquid or if the claimed filter bag can incorporate any amount of the active (therapeutic) compound and is not limited by the dosage. The art teaches administering medicaments together with tea leaves present inside the bag. Prior art (US 5,921,955) teaches incorporating a beneficial agent in a retention pocket to hold one or more beneficial agents. However, the art does not recognize incorporating probiotics, diagnostic agents or autonomic drugs, chemotherapeutic or anti-neoplastic agents etc., in the filter bags. In this regard, instant specification fails to provide details of the conditions (such as temperature) of coating or incorporating the desired agents without loosing the activity of the compounds. While preparing powder or liquid formulations of therapeutic compounds is known, the art does not recognize the instant step of incorporating in the filter bag and applicants have not provided enough guidance if the incorporation is a function of

temperature or is affected by processing conditions owing to the properties of the therapeutic compounds. Applicants refer to US patent No. 5,871,789, incorporated by reference, for making tea bags. However, the cited patent only teaches preparing tea bags but does not teach or suggest as to how to incorporated any of the vast number of the known medicaments in the art. Furthermore, instant claimed agents such as autonomic drug, phytochemical, oligosaccharide, mineral, pyruvate precursor, probiotic, diagnostic agent etc., are broad and includes besides those compounds that have not yet been identified to have such as function and may include compounds having different functional properties. Accordingly, in the absence of any guidance from the instant specification, one of an ordinary skill in the art would have to perform undue experimentation in order to identify or choose the right compound that belongs to the claimed categories, chose the amount to be incorporated, prepare an appropriate liquid or solid or a powder or other suitable form of the compound so as to apply to the filter bag and finally in the process of application of the medicament i.e., mix with the porous sheet material before forming the sheet, apply to the sheet material by affixing or spraying the medicament, sprinkle the medicament or dip the paper into medicament solution etc. Thus further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 22, 2005

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SUPERVISORY PATENT EXAMINER
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